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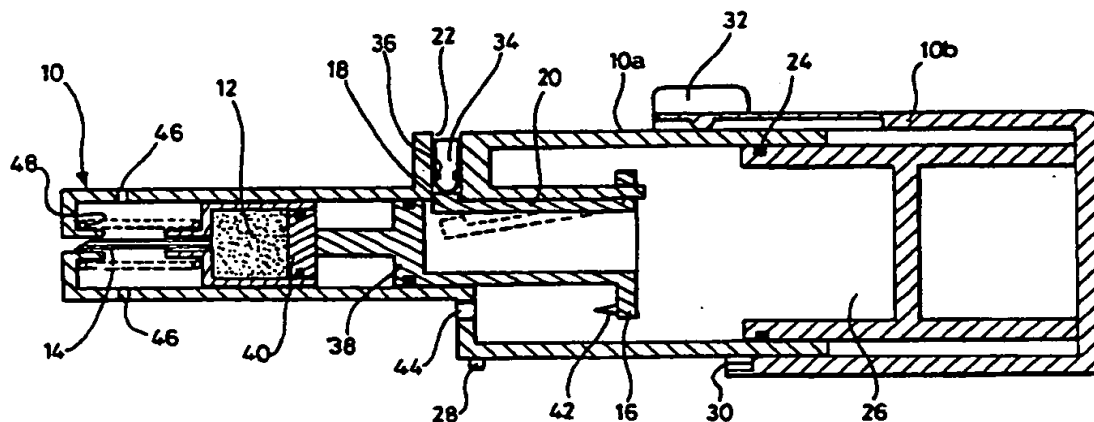
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(54) Title: SAFETY INJECTION DEVICE



(57) Abstract

Disclosed is a device for injection of a medicament into a human or animal body, the device comprising: a housing having a medicament chamber containing a medicament to be injected; an injection needle communicating with the medicament chamber; a plunger in operable linkage to the needle, said plunger and needle being movable between a storage position, in which the needle is fully retracted within the housing, and a delivery position in which at least the tip of the needle projects beyond the housing; releasable retaining means for retaining the plunger in the storage position; means for applying a propulsive force to the plunger, the propulsive force being operative, when the retaining means are released, to propel the needle from the storage position to the delivery position and then to inject the medicament from the chamber into and through the injection needle; means for reducing the propulsive force; and injection needle return means operative to return the needle from the delivery position to the storage position after the injection of the medicament.

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## SAFETY INJECTION DEVICE

### Field of the Invention

This invention relates to a device for, and method of, injection of medicaments into the body.

### Background of the Invention

A number of devices for injection into the body are known, in which the injection needle is retained within the device in a storage position and deployed into a delivery position immediately prior to injection. Such devices have the advantage of improved safety and also avoid the psychological deterrent effect of a readily visible needle. Accordingly, they are particularly suitable for use by non-medically trained personnel, especially for use as auto-injectors where the person operating the device injects his or her self.

Known devices for auto-injection are generally spring-operated. Examples of such devices include those disclosed in EP 0 516 473 and in GB 728,248. These publications describe injection devices in which one spring is used to deploy a hypodermic needle to a delivery position and to deliver an injection and a second spring is employed to retract the needle after the injection has been delivered. Accordingly, after the injection is made, work must be done in overcoming the resistance of the spring-operated means in order to retract the needle from its delivery position. This renders the device comparatively complicated and expensive to manufacture. Moreover, such devices are prone to causing multiple punctures in the body being injected, due to oscillation of the needle. There exists therefore a need for improvements upon conventional devices of the type described above.

### Summary of the Invention

In a first aspect the invention provides a device for injection of a medicament into a

human or animal body, comprising a housing having a medicament chamber containing a medicament to be injected, an injection needle communicating with the medicament chamber, a plunger in operable linkage to the needle, said plunger and needle being movable between a storage position in which the needle is fully retracted within the housing and a delivery position in which at least the tip of the needle projects beyond the housing, releasable retaining means for retaining the plunger in the storage position, means for applying a propulsive force to the plunger, the propulsive force being operative, when the retaining means are released, to propel the needle from the storage position to the delivery position and then to inject the medicament from the chamber into and through the injection needle, means for reducing the propulsive force, and injection needle return means operative to return the needle from the delivery position to the storage position after the injection of the medicament.

Preferably the propulsive force is supplied by a compressed fluid, most preferably by compressed gas. The compressed fluid may be supplied from an external source (such as a cylinder of compressed air) or, advantageously, the fluid is compressed within and supplied by the device itself. Preferably the means for reducing the propulsive force is capable of reducing the force to substantially zero.

In a preferred embodiment the housing comprises two portions with an air-tight seal therebetween, the two portions being relatively movable from an unprimed to a primed position. The two portions define an air-filled headspace of variable volume abutting the plunger, the volume of said headspace being greater in the unprimed position than in the primed position, such that relative priming movement of the two portions from the unprimed to the primed position compresses the air in the headspace, the plunger being retained in its storage position by the releasable retaining means.

Relative movement of the two portions may be by means of a sliding arrangement along an axis. This may be accomplished, for example, by simply pushing the two portions towards each other or by actuation of a lever.

Preferably one portion is located around the exterior of the other portion.

Advantageously, one portion is mounted on the other by means of a screw thread.

It is desirable that the device includes locking means operative to hold the two portions in the primed position. Conveniently such locking means comprise an arm projecting from one portion which engages a co-operating recess on the other portion when the portions are in the primed position.

The releasable retaining means conveniently comprises a manually operable trigger mechanism. It is desirable that the releasable retaining means is releasable only when the device is in the primed position, thereby preventing premature release during priming of the device.

In a preferred embodiment, the releasable retaining means comprises a projection mounted on a resiliently deformable section of the plunger which projection engages a co-operating recess or cavity in the wall of the housing, the projection being disengaged from the co-operating recess or cavity by the action of a trigger button upon a trigger pin.

The plunger preferably comprises means for preventing rotation thereof within the housing. Conveniently such means comprise a member on the plunger engaged between two guide pins mounted on the inner surface of the housing.

Desirably the plunger comprises two pistons: a first drive piston forms an air-tight seal with the inner surface of the wall of the housing, and a second medicament piston forms an air-tight seal with the inner surface of the wall the medicament chamber. When the propulsive force is applied to the plunger and the retaining means released, the drive piston serves to force the needle from the storage position to the delivery position. When the needle is in the delivery position, the medicament piston serves to expel the medicament from the medicament chamber, through the needle, and into the body.

Advantageously the means for reducing the propulsive force is linked to the operation of the device in a timed relationship, such that the propulsive force is reduced only when all or substantially all the medicament has been discharged from the medicament chamber.

In one embodiment, the plunger comprises a sharp and/or rigid projection which, when all or substantially all of the medicament has been expelled from the medicament chamber, contacts and ruptures a rupturable portion of the wall of the housing, allowing the air compressed in the headspace to escape therefrom, thereby removing the propulsive force. In an alternative embodiment there is provided a sleeve valve arrangement, in which an outer sleeve is mounted on, and movable relative to, the housing. The sleeve is movable between a closed position and an open position, such that in the closed position an aperture in the wall of the housing is covered by the outer sleeve, the sleeve preferably being retained in the closed position by retaining means. Upon actuation of the device, when all or substantially all of the medicament has been delivered, the retaining means is released and the sleeve is moved to the open position, in which the aperture in the wall of the housing is uncovered, such that air compressed in the headspace of the housing may escape through the aperture, thereby removing the propulsive force. Preferably the sleeve valve is of the "bi-stable" variety.

A number of needle return means may be envisaged.

In one embodiment, there is provided a return spring loaded between the wall of the drug chamber and the wall of the housing. Preferably the arrangement is such that the return spring is compressed by the action of the plunger on the medicament chamber, such that the spring is compressed when the needle is in the delivery position. When the propulsive force is reduced, the return spring tends to return to its former position, thereby retracting the needle within the housing. In such an embodiment it is preferred to provide the wall of the housing with one or more vents between the medicament chamber and the end of the housing from which the needle projects in the delivery position. Such vents prevent the compression of air within the housing as the medicament chamber moves from the storage to the delivery position, which compression would otherwise tend to resist the propulsive force.

In another embodiment there is provided a second headspace such that compression of the gas in the second headspace generates a return means for retracting the needle. For example, in such an embodiment one could envisage the second headspace being located

between the medicament chamber and the wall of the housing, such that advance of the medicament chamber to the primed position compresses air within the second headspace (there being no vents located in the wall of the housing), thereby providing the return means for retracting the needle.

In a preferred embodiment of the invention, the device is primed by the relative rotational movement of two portions of the housing with a helical thread in one portion engaged by the other, producing relative axial movement in response to the rotation, the two portions being locked in position by a locking detent on an outer sleeve of one of the portions engaging a co-operating recess on the other portion. Desirably the helical thread is of non-uniform pitch, such that initial rotational movement produces greater relative axial movement of the two portions than subsequent rotational movement, which is resisted by the increased pressure of air within the headspace. The device may be supplied to users in the primed or, preferably, the unprimed position. If supplied and stored in the unprimed position there is less chance of accidental discharge of the device. Moreover storage in the primed position, in which the components of the device are under stress, could lead to "creep" or deformation of synthetic plastics components.

The priming of the device results, in the preferred embodiment, of compression of air in a headspace abutting the plunger. The compressed air tends to force the plunger along the longer axis of the housing. The plunger however is held in place by releasable retaining means, comprising a projection mounted on a resiliently deformable section of the plunger, the projection releasably engaging a cavity in the wall of the housing. When the device is primed, a manually operable trigger becomes located adjacent to a trigger pin.

To use the primed auto-injection device, the needle end of the housing is placed against the skin in the spot to be injected. The trigger is activated, depressing a trigger pin, disengaging the projection mounted on the resiliently deformable section of the plunger from the cavity in the wall of the housing, thereby enabling the propulsive force of the compressed air in the headspace abutting the plunger to drive the plunger along the longer axis of the housing. The drive piston thus advances the medicament chamber and needle to the delivery position where, since the housing has been placed in contact with the skin,

the needle will penetrate the skin and enter the body. Air between the medicament chamber and the housing may be expelled by passage through one or more vents in the wall of the housing.

As the medicament chamber and needle advance to the delivery position, a return spring is compressed. When the needle and medicament chamber are fully advanced, the propulsive force serves to advance the medicament piston within the medicament chamber, thereby expelling medicament from the chamber, through the needle and into the body.

When all or substantially all of the medicament has been discharged, a spike projecting from the plunger contacts and ruptures a rupturable portion in the wall of the housing, allowing the air compressed in the headspace to escape through the rupture, thereby reducing to zero the propulsive force acting on the plunger. As the propulsive force is progressively reduced, a point is reached at which the force exerted by the compressed return spring is greater than the residual propulsive force and from this point, the return spring serves to force back the medicament chamber, thereby retracting the needle from the body back into the housing. As this return force is substantially unopposed, there is no tendency for the needle to oscillate, and the device does not cause multiple puncture wounds.

It will be apparent that the relative forces resisting advance of the needle and medicament chamber (caused by the drive piston) and those resisting expulsion of the medicament from the medicament chamber through the needle (caused by the medicament piston), should desirably be adjusted so as to prevent premature expulsion of the medicament occurring before the needle and medicament chamber reach the delivery position.

Forces resisting advance of the medicament chamber within the housing may include: static and sliding friction between the walls of the medicament chamber and the housing, resistance to the advance of the needle (whether caused by friction or entry into the subject's body), and overcoming the resistance of the return means.

Forces resisting expulsion of the medicament include static and sliding friction between

the medicament piston and the walls of the medicament chamber. In addition it is preferred to generate sufficient pressure within the medicament chamber to give a significant flow rate of the medicament through the needle.

In general, it is desired that forces resisting expulsion of the medicament are optimally maximised (within reasonable levels) whilst those resisting advance of the needle and medicament chamber are optimally minimised. For example, resistance to flow of the medicament can be maximised by selection of a relatively long, fine bore needle (which selection has the advantage of minimising resistance of the subject's body to the needle and minimising the subject's discomfort). Frictional forces between the medicament piston and the medicament chamber can be optimally maximised by the choice of materials, whilst those frictional forces between the medicament chamber and the housing may be optimally minimised by the selection of appropriate materials and lubricants.

In a further aspect the invention provides a method of delivering a liquid through a rupturable surface, comprising: placing adjacent to the rupturable surface a device comprising a housing having a chamber retaining the liquid to be delivered, a needle communicating with the chamber, a plunger in operable linkage to the needle, said position in which the needle is fully retracted within the housing and a delivery position in which at least the tip of the needle projects beyond the housing, releasable retaining means for retaining the plunger in the storage position, means for applying a propulsive force to the plunger, the propulsive force being operative, when the retaining means are released, to propel the needle from the storage position to the delivery position and then to deliver the liquid from the chamber, into and through the needle. means for reducing the propulsive force, and needle return means operative to return the needle from the delivery position to the storage position after the delivery of the liquid; and activating the device so as to deliver the liquid.

Desirably the liquid is a medicament. Advantageously the rupturable surface is the skin of a human or animal body.

The invention will now be explained further by way of illustrative example and with

reference to the drawings of which:

Figure 1 shows a longitudinal section of a first embodiment of the device;

Figure 2a-e are representations showing operation of the first embodiment of the device in sequence;

Figure 3 shows a longitudinal section of a second embodiment of the device; and

Figure 4a-e are representations showing operation of the second embodiment of the device in sequence.

#### Specific Description of Embodiments

In one embodiment, a device (Figure 1) for injection of a medicament into a human or animal body comprises a housing 10 of a moulded synthetic plastics material. The housing 10 accommodates a medicament chamber 12 containing a medicament to be injected, a hollow-bore stainless steel needle 14 communicating with the medicament chamber 12, and a synthetic plastics material plunger 16 in operable linkage to the needle 14, the plunger 16 and the needle 14 being movable between a storage position (Figure 2a) in which the needle is fully retracted within the housing and a delivery position (Figures 2c-2d) in which at least the tip of the needle projects beyond the housing.

The device also includes releasable retaining means for retaining the plunger 16 in the storage position, the retaining means comprising a projection 18 mounted on a resiliently deformable section 20 of the plunger 16, the projection 18 engaging a recess 22 in the wall of the housing 10.

The device further comprises means for applying a propulsive force to the plunger 16, the propulsive force being operative, when the retaining means are released, to propel the needle 14 from the storage position (Figure 2a) to the delivery position (Figure 2c) and then to inject the medicament from the chamber 12 into and through the needle 14 (Figure

2d), means for reducing the propulsive force, and needle return means operative to return the needle 14 from the delivery position to the storage position after injection of the medicament.

In the embodiment shown in Figure 1, the housing comprises two portions (10a, 10b) with a gasket 24 forming an air-tight seal therebetween. The two portions 10a and 10b are relatively movable from an unprimed (Figure 2a) to a primed (Figure 2b) position and define an air-filled headspace 26 of variable volume abutting the plunger 16. The volume of the headspace 26 is greater in the unprimed position than in the primed position, such that relative priming movement of the two portions 10a and 10b from the unprimed to the primed position compresses the air in the headspace, the plunger 16 being retained in the storage position by the releasable retaining means.

In the embodiment shown in Figure 1, the device is primed by relative rotational movement of the two portions 10a and 10b, with a helical thread on the outer surface of 10a engaged by 10b, producing relative axial movement in response to the rotation. The helical thread on the portion 10a is of non-uniform pitch, such that initial rotational movement produces greater relative axial movement than subsequent rotational movement, which is resisted by the increased pressure of air within the headspace.

The two portions 10a and 10b are locked in the primed position by a locking detent 28 projecting from the portion 10a which engages with a snap fit a co-operating recess 30 in the portion 10b when the two portions 10a and 10b are moved into the primed position.

The portion 10b includes a manually operable trigger button 32 which, when the two portions 10a and 10b are moved into the primed position, becomes located adjacent to a trigger pin 34 retained within the recess 22 by an air-tight gasket 36. Actuation of the trigger button 32 depresses the trigger pin 34, deforming the resiliently deformable section 20 of the plunger 16, thereby disengaging the projection 18 from the recess 22. The resiliently deformable section 20 and the projection 18 mounted thereon are shown in the released position as a dotted line in Figure 1.

The plunger 16 comprises a drive piston 38 forming an air-tight seal with the inner surface of the wall of the housing 10, and a medicament piston 40 forming an air-tight seal with the inner surface of the wall of the medicament chamber 12. The plunger 16 also comprises a rigid, sharp projection 42 which, when substantially all of the medicament has been expelled from the medicament chamber 12, contacts and ruptures a rupturable diaphragm 44 in the wall of the housing 10.

The device further includes vents 46 and needle return means comprising a needle return spring 48 located between the medicament chamber 12 and the end wall of the housing 10. The device is stored and supplied in the unprimed storage position shown in Figure 2a, in which the needle 14 is fully retracted within the housing 10.

To perform an injection, the device is first primed by the user. Relative rotational movement of the two portions 10a and 10b produces relative axial movement of the portions 10a and 10b due to the screw thread engagement. Eventually the locking detent 28 engages co-operating recess 30 and the two portions are locked in the primed position (Figure 2b), in which the volume of the headspace 26 is greatly reduced. The compressed gas therein thus provides a propulsive force.

Movement from the unprimed to the primed position also brings the trigger button 32 adjacent to the trigger pin 34.

Thus, to deliver the medicament, the end of the housing 10 is placed against the skin and the trigger button 34 is actuated. This disengages the projection 18 from the co-operating recess 22, allowing the propulsive force of the gas compressed in the headspace 26 to act on the plunger 16 so as to propel the plunger 16 the medicament chamber 12 and the needle 14 from the storage position (Figure 2b) to the delivery position (Figure 2c), in which the needle 14 projects from the housing 10. As the medicament chamber 12 advances within the housing it tends to compress the return spring 48. Air displaced by the advance of the medicament chamber 12 passes through the vents 46. When the medicament chamber 12 and the needle 14 are fully advanced, further movement of the medicament chamber 12 is resisted by contact with the housing 10. The propulsive force

still acting on the plunger 16 then causes the medicament piston 40 to advance within the medicament chamber 12, thereby expelling the medicament from the medicament chamber 12 and through the needle 14.

When substantially all of the medicament has been expelled, the projection 42 comes into contact with and ruptures the rupturable diaphragm 44 (Figure 2d). The compressed gas in the headspace 26 can thus escape through the ruptured membrane until the air pressures in the headspace 26 and outside the device are equalised, removing the propulsive force. As the propulsive force is progressively removed, a point is reached at which the force exerted by the compressed return spring 48 is greater than the residual propulsive force and, from this point, the return spring 48 serves to force back the medicament chamber, thereby retracting the needle 14 back into the housing 10 (Figure 2e).

In a second embodiment (Figure 3), the device comprises a housing 10 comprising two portions 10a and 10b. As in the previously described embodiment, the housing 10 accommodates a medicament chamber 12, a hollow-bore stainless steel needle 14 communicating with the medicament chamber 12, and a synthetic plastics material plunger 16 in operable linkage to the needle 14, the plunger 16 and the needle 14 being movable between a storage position (Figure 4a) in which the needle is fully retracted within the housing and a delivery position (Figures 4c-4d) in which at least the tip of the needle 14 projects beyond the housing 10.

The device also includes releasable retaining means for retaining the plunger 16 in the storage position, the retaining means comprising a projection 18 mounted on a resiliently deformable section 20 (shown in dotted lines in Figure 3) of the plunger 16, the projection 18 engaging a co-operating recess 22 in the wall of the housing 10.

In the embodiment shown in Figure 3, there is a gasket 24 forming an air-tight seal between the two portions 10a and 10b, which are relatively movable from an unprimed position (Figure 4a) to a primed position (Figure 4b) and define an air-filled headspace 26 of variable volume abutting the plunger 16. The volume of the headspace 26 is greater in the unprimed position than in the primed position, such that relative priming movement

of the two portions compresses the air in the headspace 26.

The two portions 10a and 10b are locked in the primed position by arrow-head locking detents 28, each detent 28 being mounted on a resiliently deformable arm 30 depending from the portion 10b, the detents 28 engaging co-operating recesses 34 in the portion 10a when the two portions 10a and 10b are moved into the primed position.

In the primed position, the resiliently deformable angled arms 30 are held in position by a cup-shaped guide member 40, the arms 30 being located in slots 46 in the side wall of the guide member 40, through which the locking detents 28 project to engage the co-operating recesses 34.

The portion 10b includes a manually operable trigger button 32 which, when the two portions 10a and 10b are moved into the primed position, becomes located adjacent to the projection 18. Actuation of the trigger button 32 depresses the projection 18, deforming the resiliently deformable section 20 of the plunger 16, thereby releasing the projection 18 from the co-operating recess 22.

The device further comprises fingers 36 projecting from the end of the plunger 16. When the device is primed, the fingers 36 pass through slots 38 in the end wall of the guide member 40. The shape of the fingers 36 is such that they pass through the slots 38 during the priming of the device, but engage the end wall of the guide member 40 when the direction of the relative movement of fingers 36 and the guide member 40 is in the opposite direction.

In addition, the plunger 16 comprises two projecting arms 42 situated towards the end region of the plunger closer to the medicament chamber. These arms 42 are of resiliently deformable synthetic plastics material held in compression between the plunger and the wall of the housing 10a.

To perform an injection, the device is primed by the user. Relative movement of the portions 10a and 10b results in the arrow-head locking detents 28 engaging co-operating

recesses 34 (Figure 4b). Air in the headspace 26 is greatly compressed, providing a propulsive force. Further, the trigger button 32 is brought into position adjacent to the projection 18 mounted on the resiliently deformable section 20 of the plunger 16.

To deliver the medicament, the end of the housing 10a is placed against the skin and the trigger button 32 actuated. This disengages the projection 18 from the co-operating recess 22, allowing the gas compressed in the headspace to propel the plunger 16 and the needle 14 from the storage position to the delivery position (Figure 4c). When the medicament chamber 12 and the needle 14 are fully advanced, further movement of the medicament chamber 12 is resisted by contact with the housing 10. The propulsive force still acting on the plunger 16 then causes the plunger 16 to advance within the medicament chamber 12, thereby expelling the medicament from the medicament chamber 12.

When substantially all of the medicament has been expelled from the medicament chamber 12, the resiliently deformable projections 42 are brought, by the relative movement of the plunger 16 within the medicament chamber 12, into position adjacent co-operating recesses 44 in the wall of the chamber, and engage the recesses 44 with a snap fit. In addition, immediately prior to the point at which the plunger 16 is furthest advanced within the housing 10, the projecting fingers 36 engage the end wall of the guide member 40 and pull the guide member 40 slightly along the longer axis of the device.

As the fingers 36 pull the guide member, relative movement of the guide member 40 and the resiliently deformable angled arms 30 forces the detents 28 to disengage from the co-operating recesses 34. Accordingly, the residual compressed air in the headspace 26 serves to push back the portion 10b from the portion 10a. When the deformable arms 30 are in their unstressed position, the locking detents 28 are disengaged from the co-operating recesses 34 and instead engage the slots 46 in the guide member 40 and tend to pull the guide member back to its storage position. Since the projecting fingers 36 of the plunger 16 are engaged with the guide member 40, and since the projecting arms 42 of the plunger 16 are engaged with the recesses 44 in the medicament chamber 12, the medicament chamber 12 and the needle 14 are also returned to their storage position.

Claims

1. A device for injection of a medicament into a human or animal body, comprising: a housing having a medicament chamber containing a medicament to be injected; an injection needle communicating with the medicament chamber; a plunger in operable linkage to the needle, said plunger and needle being movable between a storage position, in which the needle is fully retracted within the housing, and a delivery position in which at least the tip of the needle projects beyond the housing; releasable retaining means for retaining the plunger in the storage position; means for applying a propulsive force to the plunger, the propulsive force being operative, when the retaining means are released, to propel the needle from the storage position to the delivery position and then to inject the medicament from the chamber into and through the injection needle; means for reducing the propulsive force; and injection needle return means operative to return the needle from the delivery position to the storage position after the injection of the medicament.
2. A device according to claim 1, wherein the housing comprises two portions, with an air-tight seal therebetween, which define an air-filled headspace of variable volume abutting the plunger, the two portions being relatively movable from an unprimed position to a primed position, such that the volume of the headspace is greater in the unprimed position than in the primed position.
3. A device according to claim 2, wherein one portion is located around the exterior of the other portion.
4. A device according to claim 2 or 3, wherein priming is effected by relative rotational movement of the two portions of the housing, with a helical thread in one portion engaged by the other, so as to produce relative translational movement in response to the rotational movement.
5. A device according to claim 4, wherein the helical thread is of non-uniform pitch.
6. A device according to any one of the preceding claims, wherein the releasable retaining means is releasable only when the device is in the primed position, so as to

prevent premature release of medicament during priming of the device.

7. A device according to any one of the preceding claims, comprising locking means to hold the device in the primed position.

8. A device according to any one of the preceding claims, wherein the propulsive force is supplied by a compressed fluid.

9. A device according to any one of the preceding claims, wherein the propulsive force may be reduced in a timed relationship to the operation of the device, such that the propulsive force is reduced only when substantially all of the medicament has been discharged from the medicament chamber.

10. A device according to any one of the preceding claims, wherein the propulsive force is reduced by venting a compressed fluid from a headspace in the housing abutting the plunger.

11. A device according to claim 10, wherein venting of the compressed fluid is effected by a rigid and/or sharp projection on the plunger rupturing a rupturable portion of the wall of the housing.

12. A device according to claim 10, wherein venting is effected by means of a sleeve valve arrangement.

13. A device according to any one of the preceding claims, wherein the injection needle return means comprises a return spring located between the wall of the drug chamber and the wall of the housing.

14. A device according to claim 13, wherein one or more vents are provided in the wall of the housing between the medicament chamber and the end of the housing from which the needle projects in the delivery position.

15. A device according to any one of claims 1 to 12, wherein the needle return means comprises a gas-filled return headspace, such that compression of the gas in the return headspace generates a return force to retract the needle.

16. A device according to claim 15, wherein the return headspace is located between the medicament chamber and the wall of the housing, such that advance of the medicament chamber to the primed position compresses the gas within the return headspace.

17. A device for injection of a medicament substantially as hereinbefore described and with reference to the accompanying drawings.

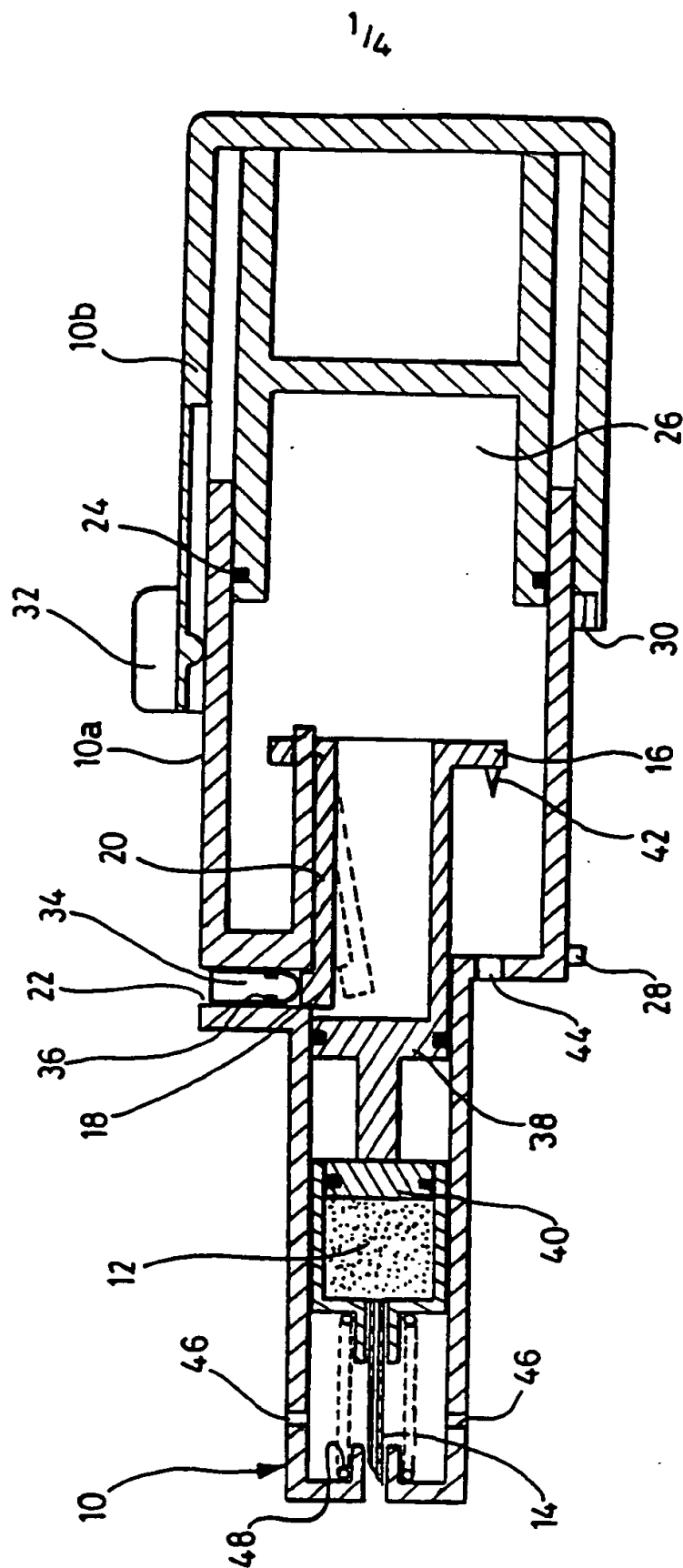


Fig. 1

SUBSTITUTE SHEET (RULE 26)

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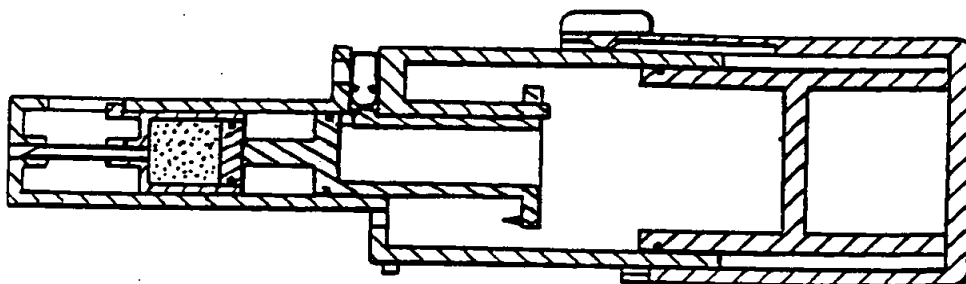


Fig. 2(a)

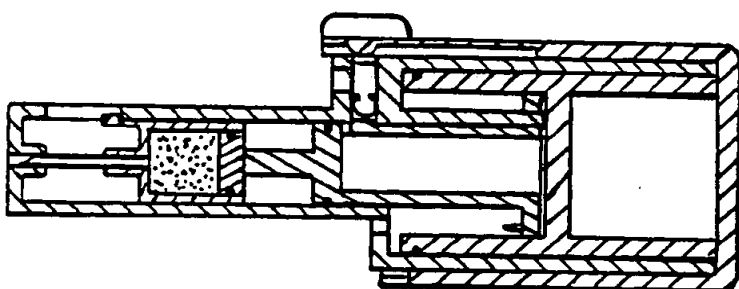


Fig. 2(b)

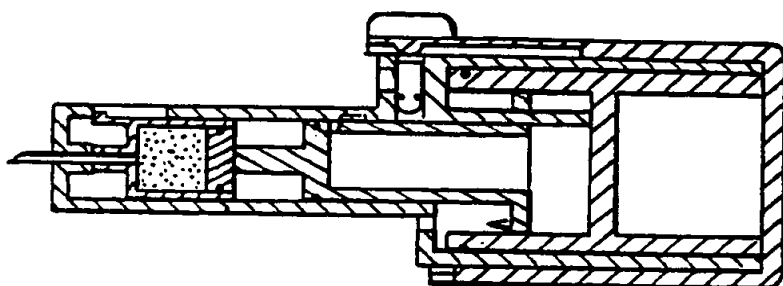


Fig. 2(c)

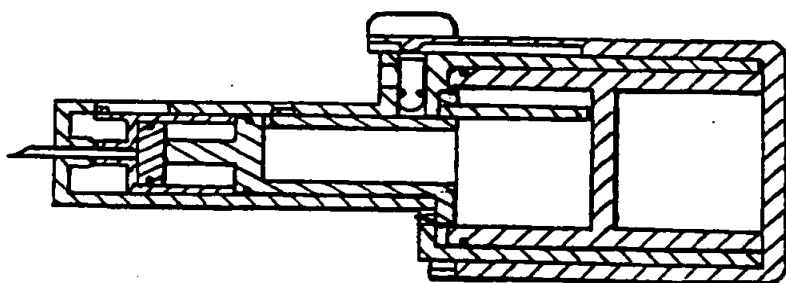


Fig. 2(d)

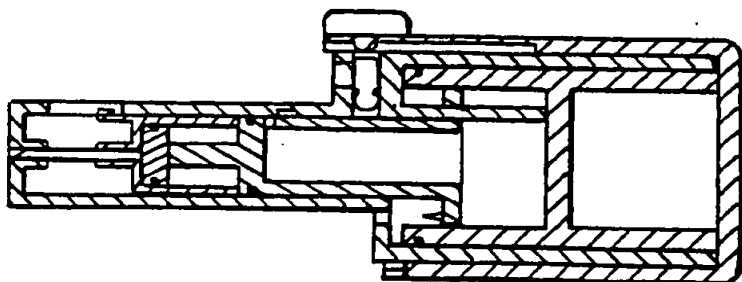


Fig. 2(e)

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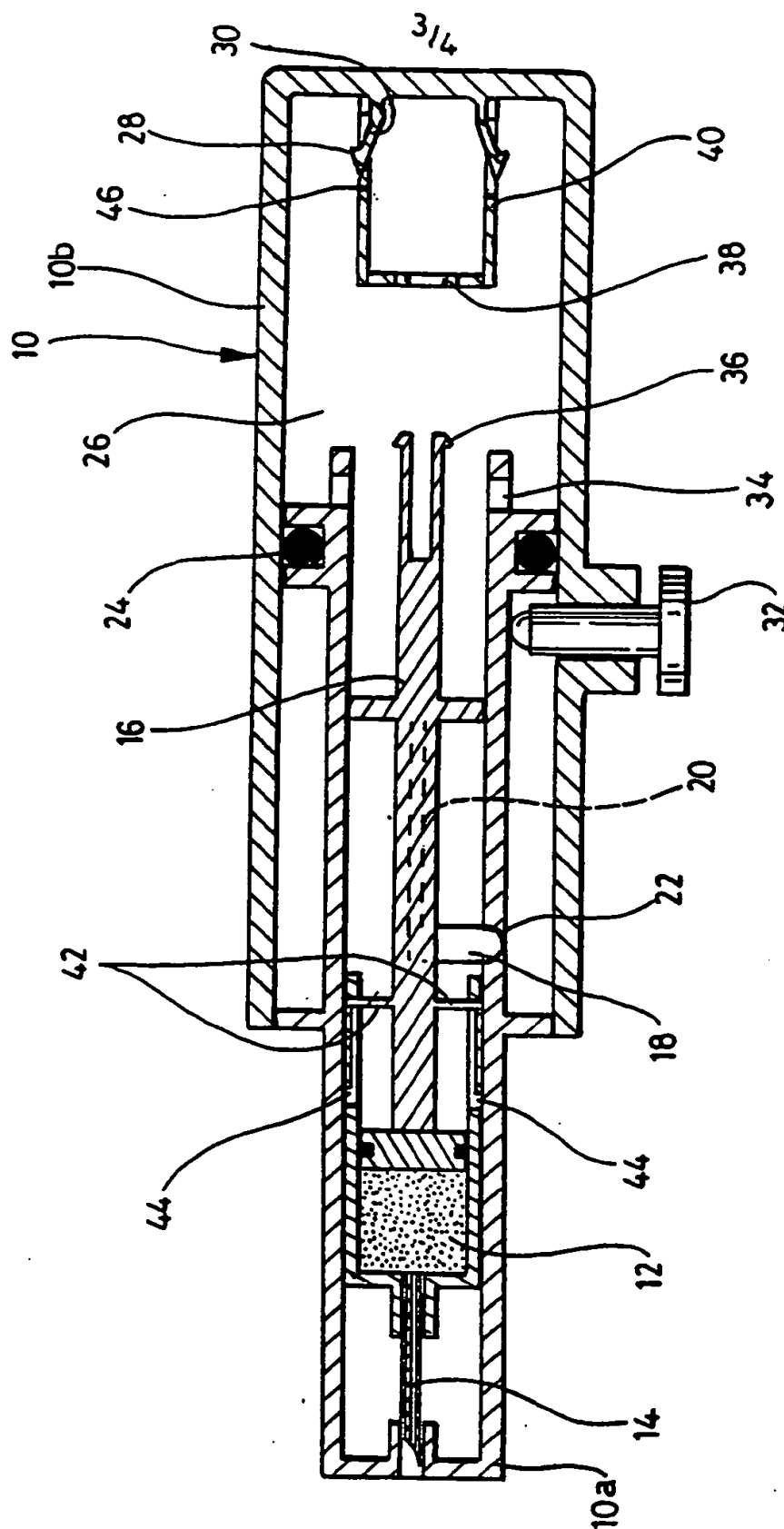


Fig. 3

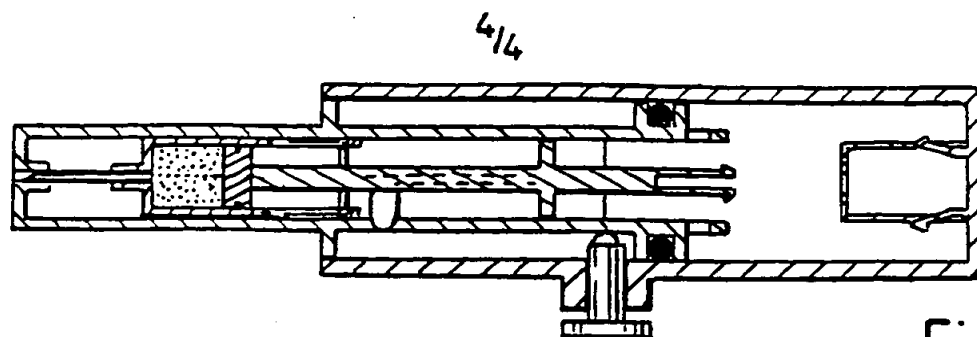


Fig. 4 (a)

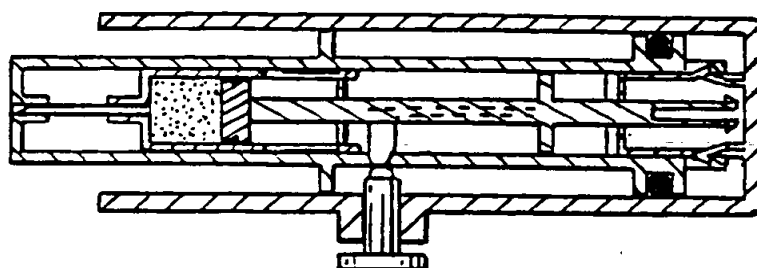


Fig. 4 (b)

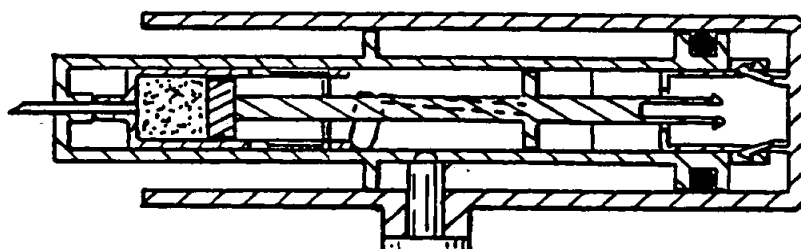


Fig. 4 (c)

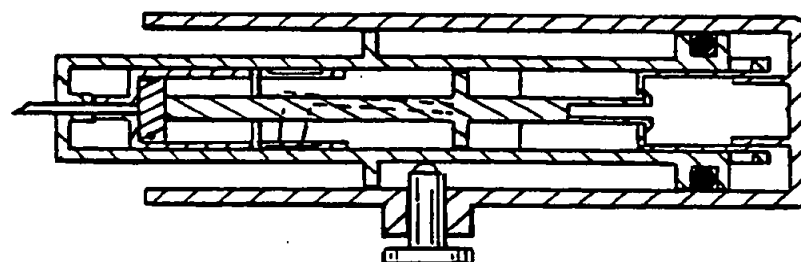


Fig. 4 (d)

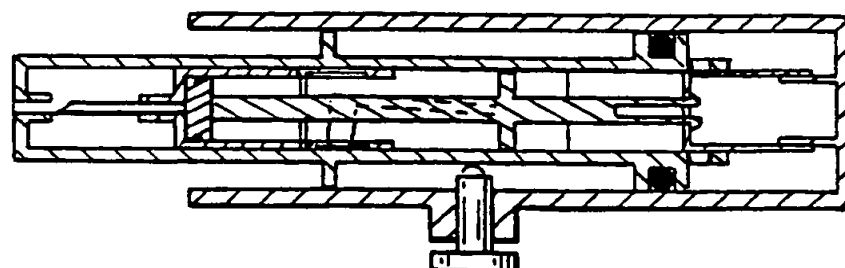


Fig. 4 (e)

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB 95/00940

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 6 A61M5/20 A61M5/32		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,3 977 402 (PIKE) 31 August 1976 see column 5, line 35 - column 6, line 55; figures 1,2 ---	1-16
Y	US,A,5 049 133 (JOEÉ VILLEN PASCUAL) 17 September 1991 see column 2, line 25 - line 56; figures 1,2 ---	1-16
A	WO,A,92 19296 (KRAMER) 12 November 1992 see page 8, line 10 - page 9, line 35; figures 1,2 ---	1-16
A	EP,A,0 516 473 (OWEN MUMFORD LIMITED) 2 December 1992 see column 2, line 35 - column 4, line 37; figures 1-4 --- -/--	1
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art *&* document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
18 September 1995		13.10.95
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016		Authorized officer  Ehrsam, F

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International Application No  
PCT/GB 95/00940

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CH,A,518 102 (HENKE GMBH) 31 January 1972 see column 5, line 19-32; figure 2 ----	1
A	US,A,4 717 384 (WALDEISEN) 5 January 1988 see column 5, line 55 - column 6, line 60; figures 1-8 -----	1

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International Application No  
PCT/GB 95/00940

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US-A-4717384	05-01-88	NONE	

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